



Document Name: Annexure-8 (Chemical & Instrumental Analytical Results)

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Annexure-8

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Sr. No.	Sampling Location	Batch Number of Previous Product			Acceptance limit
1.	Fluid Bed Dryer				
	FBD Bowl (A) sieve				
	FBD Bowl (B) sieve				
	Internal surface of FBD bowl (A)				
	Internal surface of FBD bowl (B)				
	Internal surface of chamber				
	View window				
	Lower plenum				
	Upper plenum				
	Plenum gaskets				
2.	Rapid Mixer Granulator				
	Impeller				
	Chopper				
	Discharge port				
	Lid gasket				
	Internal surface of bowl				
	Loading port				
	Internal surface of lid				
	Discharge port gasket				
	Bottom surface of bowl				
3.	Vibro Sifter				
	Lower hopper				
	Lid				
	Upper hopper				
	Discharge chute				
	Internal surface of lid				
	Sieve				



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4.	Blender Bin				
	Inner surface of bin				
	Discharge port				
	Inner surface of charging port				
5.	Compression Machine				
	Connector				
	Powder hopper				
	Force feeder				
	Tablet discharge chute				
	Turret				
	Rejection box				
	Gloves surface				
	Base plate of isolator				
	Isolator panel				
6.	Deduster				
	Inlet chute				
	Outlet chute				
	Spiral disc				
7.	Metal detector				
	Feeding chute				
	Outlet chute				
	Rejection box				
8.	Glove Box				
	Deflector plate				
	Spool piece				
	Inner surface				
	Gloves surface				



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9.	Paste Kettle				
	Inner surface				
	Stirrer				
10.	Blister Machine				
	Hopper				
	Bowl disc				
	Feeding box & channel				
11.	Be- Coater				
	Inner surface of coating pan				
	Baffle				
	Discharge chute				
	Spray gun assembly				
	Internal surface of view window				
12.	Dispensing Isolator				
	Glove surface				
	Cage blender (inner surface)				
	Vibro sifter (inner surface)				
	Rapid transfer port				
	Isolator inner surface				
	Isolator front cover (inner surface)				
13.	Cone Mill				
	Charging port				
	Screen				
	Milling chamber				
	Blade assembly				
	Discharge port				



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14.	Tipper				
	Inner surface				
	Discharge port				
	Gasket groove				
15.	Sampling and Cleaning Station				
	Bottom surface				
	Sampling station				
	Spray ball mounting plate				
	Gloves surface				
	Spray ball				
16.	Blister Machine (Alu-Alu)				
	Hopper				
	Bowl disc				
	Feeding box				
	Feeding channel				
17.	IPQC Isolator				
	Glove surface				
	Rapid transfer port				
	Isolator inner surface				
	Isolator front cover (inner surface)				
18.	Solution preparation vessel				
	Inner surface of lid				
	Stirrer				
	Inner surface of vessel				



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19.	Scoop				
	Scoop surface				
20.	Sampling rod				
	Inner surface of tube				
21.	Spatula				
	Spatula surface				
Cumulative value (ppm/mcg/ml)					

Conclusion: _____

Checked By:
(Signature/Date)

Verified By:
(Signature/Date)

Approved By:
(Signature/Date)